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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,179	07/27/2001	Pantaleone Paul Masci	65064/133	2781

7590 09/22/2004
John P Isacson
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Washington, DC 20007-5109

EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,179	Applicant(s) MASCI ET AL.	
	Examiner B. Dell Chism	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 41-45, 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40, 46 and 49-55 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

DETAILED ACTION

1. This Office Action is in response to Applicants' papers filed 22 June 2004. Claims 1-40, 46 and newly submitted claims 49-55 are under consideration, and claims 41-45, 47 and 48 are withdrawn from consideration.

Withdrawal of Objections and Rejections

2. The rejections and/or objections made in the prior office action filed 13 February 2004, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 22 June 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Objections

3. (Necessitated by Amendment) Claim 8 is objected to because of the following informalities: claim 8 itemized sequences from (a)-(e) and then struck through (f) wherein (f) should be maintained. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. (Maintained and Necessitated by Amendment) Claims 1-40, 46 and 49-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, for reasons presented in the previous office action, is not enabled for in vivo alleviation of blood loss. For those reasons of the last office action, and because the specification clearly indicates the unpredictability of its own data by stating that the validity of the results need further scrutiny because the assay was for

Art Unit: 1654

in vitro and subject to error. Thus, the rejection is maintained in part and necessitated by amendment in part.

5. (New) Claims 9 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 49-51 do not comply with the sequence rules, MPEP § 2422.03. The claims comprise amino acid sequences with at least four consecutive natural amino acids; thus, they require a sequence identifier, i.e., SEQ ID NO:. Furthermore, claims 49-51 are drawn to internal fragments of sequences in the drawing (Figure 11), however, there is neither a sequence identifier for the drawings nor is there a sequence identifier in the Brief Description of the Drawings (see MPEP § 2422.02). Thus, these claims are indefinite.

Also, Claim 9 is rejected for the indefinite recitation of the phrase “X is any amino acid”, wherein it is vague as to whether this is limited to the 20 naturally occurring amino acids or to all possible natural and unnatural amino acids.

Claim Rejections - 35 USC § 102

6. (Withdrawn) Rejection of Claims 1-40 and 46 under 35 U.S.C. 102(a) as being anticipated by Masci *et al.* 1999 (previously cited) is withdrawn as obviated by Applicants’ explanation of the current status of the Oath and Declaration.

7. (Withdrawn) Rejection of Claims 1 and 5-6 under 35 U.S.C. 102(b) as being anticipated by Willmot *et al.* 1995 (previously cited) is withdrawn, wherein the rejection obviated by Applicants’ amendment.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. (New) Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willmott *et al.* 1995 (cited previously). This rejection flows from the previous rejection under 35 U.S.C. 102(b), wherein the Examiner applied Willmott *et al.* as anticipatory prior art, however, Applicants' amendments took the anticipation out of Willmott *et al.* by adding the limitation of "at least 60%" with respect to "substantially pure". Applicants' went on to argue that the Willmott *et al.* art had a mixture of two plasmin inhibitors that, by Applicants' own assays, was only about 50% of the final mixture. However, the fact remains that the Willmott *et al.* reference still discloses a bioactive single stage competitive plasmin inhibitor as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further purify the bioactive single stage competitive plasmin inhibitor beneficially taught by Willmott *et al.* for the following reasons. The advantages of further purifying a partially-purified bioactive peptide such as the plasmin inhibitor disclosed by Willmott *et al.*, for which substrates have been recognized and for which a use is known, provide sufficient reason to find the purified inhibitor to have been obvious to one of ordinary skill at the time of the invention. Some of the advantages of the purification being, that purified peptides: are more storage-stable; generally exhibit an increased specific activity; are amenable to amino acid sequencing which

Art Unit: 1654

can lead to recombinant means of enzyme production with its accompanying savings in costs; and, allow for ready separation of reaction products as compared to separations which must account for impurities. These advantages are well known to the artisan of ordinary skill. Such knowledge may provide the suggestion to modify the explicit teachings of the relied upon reference. See *Ashland Oil, Inc. v. Delta Resins & Refraction, Inc.*, 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985). The position taken is that well known purification techniques would be employed with a reasonable expectation of success in providing a purified product possessing the claimed properties. Thus, an "obvious to try" standard is not being applied herein. See *In re O'Farrell*, 853 F.2d 894; 7 USPQ2d 1673 (Fed.Cir. 1988).

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the dissociation constant ranges of the claimed plasmin inhibitor differs, and if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicant.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on 571-272-0974. The fax phone number for

Application/Control Number: 09/700,179

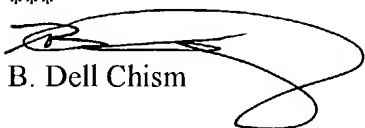
Page 6

Art Unit: 1654

the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism



CHRISTOPHER R. TATE
PRIMARY EXAMINER